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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,096	11/19/2001	Anke Rattenholl	13028-002001	2974

7590 07/07/2005

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EXAMINER	
HAYES, ROBERT CLINTON	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,096	RATTENHOLL ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes, Ph.D.	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-7 and 9-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 4/27/05 has been entered.

2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

3. Applicant's arguments filed 4/27/05 have been fully considered but they are not deemed to be persuasive.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 8 & 20 are rejected under 35 U.S.C. 102(b) as anticipated by Edwards et al (U.S. Patent 5,683,894), for the reasons made of record in Paper No: 20050124, and as follows.

Applicants argue on pages 6-7 of the response that the claims are "drawn to a pharmaceutical preparation containing proNGF as the active ingredient", and then incorrectly assume that "[i]t is generally believed that proNGF is inactive and only becomes activated upon removal of the proprotein sequence". Applicants then argue that Edwards teach in column 9 that "**undigested proNGF was inactive**". In contrast to Applicants' assertions, column 9 only states

that a given preparation "exhibited little... activity", which is not equivalent to being "inactive". Little activity is still activity, even in the one example pointed out by Applicants in column 9. The issue remains that Edwards structurally teach the identical proNGF protein as claimed in the instant application, and as Applicants acknowledge by their statement that "Edwards teaches in vitro expression of a proNGF protein in Example 2". Any subsequent processing of proNGF taught by Edwards in Examples 4, 5A or 5B is immaterial to the fact that Edwards teach how to make the proNGF product, and alternatively only supports the argument that cells will naturally and automatically process the pro-drug, proNGF, into a more active molecule/ingredient. In other words, it is immaterial whether proNGF is more active before or after processing by the cell, because Edwards' proNGF is not "inactive", as asserted by Applicants. Nevertheless, the current claims are directed to a product, which Edwards teach how to make in a pharmaceutically acceptable carrier, as claimed, and which inherently possesses any inherent property associated with proNGF. Additionally, whether, or not, proNGF is "properly folded" "by [subsequent] denaturation and renaturartion processes" to exhibit more activity is also immaterial to whether, or not, Edwards et al structurally teach compositions comprising proNGF, which again inherently has activity, by definition. Finally, it is noted that no claims to methods of denaturation and renaturation processes were elected in this application. Therefore, arguments directed to such method steps are moot.

In arguendo, no product-by-process steps are recited in the current claims. Even if such steps were recited, the issue would then become that if the product in a product-by-process claim (i.e., proNGF) is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe,* 227 USPQ 964,

966 (Fed. Cir. 1985): *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983). It has further been established by the courts that a product (i.e., the proNGF product) inherently possesses characteristics of that product (i.e., possesses any activity inherent to the protein), and that:

"the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Accordingly, since the issue in the present appeal is whether the prior art factor is identified or patently indistinct from that of the material on appeal, appellants have the burden of showing that inherency is not involved". *Ex parte Gray,* 10 USPQ 2d 1922 (1989); *In re Best,* 195 USPQ 430 (CCPA 1976).

Lastly, it is noted that the courts have held that when the prior art product reasonably appears to be the same as that claimed, but differs by process in which it is produced, a rejection of this nature is eminently fair and the burden is upon the appellants to prove, by comparative evidence, a patentable difference (*In re Brown*, 173 USPQ 685 (1972)).

In summary, Edwards et al teach how to make a pharmaceutical composition containing recombinant pro-NGF-beta solution in 50 mM NaCl/100 mM Tris (pH 7.6) (col. 8, Example 8; col. 5; col. 7, Example 2) "for comparison with active NGF-beta" (col. 7, lines 9-10), which inherently is an active ingredient itself, and which alternatively can be cleaved by NGF-gamma or trypsin to generate NGF-beta (e.g., col. 5; col. 7, Example 3; col. 8, Example 5) either *in vitro* or *in vivo*. Pharmaceutical compositions are further described in column 10 (and col. 8) using phosphate buffered saline (PBS).

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert C. Hayes, Ph.D.
July 5, 2005

ROBERT C. HAYES, PH.D.
Primary PATENT EXAMINER